

# UNIVERSITY OF PENNSYLVANIA

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## School of Medicine

Department of Biochemistry and Biophysics  
D501 Richards Building  
Philadelphia, PA 19104-6089  
Phone (21 5) 898-4342  
FAX (21 5) 898-1806

October 4, 1993

Michael R. Taylor  
Deputy Commission for Policy  
Reference Docket 93 N-0044

Patricia Dubill  
Center for Devices and Radiological Health (HFZ-84)

Department of Health and Human Services  
Food and Drug Administration  
21 CFR Part 1040  
5600 Fishers Lane  
Rockville, MD 20857

Dear Colleagues:

I've read with interest your notice of intent to allow higher intensities of light in medical devices operating in the near infrared region. I can heartily support your intent on a number of standpoints.

Item 1. 1. Many devices are not intended for irradiating the eye.

2. The main energy deposition is in the skin and the intensities employed are well below ANSI standards for skin irradiation, as I understand it, 1 milliwatt/cm<sup>2</sup> in this region.

3. There is a great and pressing need to use laser diode in a variety of instruments for which there may be important and economical and safe applications for measuring tissue properties of the breast, the brain, etc.

4. With respect to duration, a hundred seconds is more than adequate, exposure times could be limited to 30 seconds since many clinical studies require that data output be available within such a time interval.

Item 4. I do recommend that a distinction between pulsed and rapidly oscillated light intensities be made.

Item 7. I agree that the 7 mm aperture would much more properly be 3 mm.

Items 12 and 13 make good sense.

Restriction of remarks. This respondent does not consider himself to be expert in classes above 1.

93N-0044

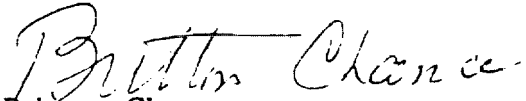
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Finally, the respondent takes note that medical devices are not specifically treated in this notice of intent and feels they are worthy of special consideration. For example in finger, brain and breast **oximetry**, the device can be attached to the particular organ prior to turning on the laser power and thus higher intensities might be appropriate.

You can certainly say in your **letter** please call upon me if you wish clarification or more details of my experience with research studies of **medical** devices under appropriate IRB approval.

Very sincerely yours,

A handwritten signature in cursive script that reads "Britton Chance".

**Britton Chance**

**Eldridge** Reeves Johnson  
University Professor Emeritus  
of Biochemistry and Biophysics  
and **Physical** Biochemistry and  
**Radiologic** Physics

BC:mmg

ROUTING SLIP  
GENERATED BY: HF-40  
DATE: OCT 22,1993

FDA CONTROL NUMBER: 935170

TRACER # 0s #:

DATE OF CORRESPONDENCE 10/04/93

DATE INTO FDA: 10/22/93

TO: MICHAEL R TAYLOR I-IF-22

FROM: BRITTON CHANCE, UNIVERSITY OF PENNSYLVANIA SCHOOL OF MEDICINE  
ELDRIDGE R JOHNSON, UNIVERSITY OF PENNSYLVANIA SCHOOL OF MEDICINE

SYNOPSIS WRITES IN SUPPORT OF FDA'S PROPOSAL TO ALLOW HIGHER INTENSITIES  
OF LIGHT IN MEDICAL DEVICES OPERATING IN THE NEAR INFRARED REGION

LEAD OFFICE: HF-40

DOCUMENT STATUS ACTIVE

HOME OFFICE: HF-40

CONTACT/PHONE#: WANDA RUSS 301-443-39(H)

COPIES: HFZ-1

HFA-305

HF-40 ANNE M BACH

I-IF-11 NANCY B YEATES

COORDINATION:

SIGNATURE REQUIRED DEPUTY COMMISSIONER FOR POLICY

REFERRALS FROM HF-40

ASSIGNED TO	ACTION	DUE DATE
HF-40 GANGLOFL	PREPARE RESPONSE FOR SIGNATURE	11/07/93
REMARKS: ACKNOWLEDGEMENT LETTER -- PER NYEATES		

EC 93 No 16 10006  
MANAGEMENT BOARD